



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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Subject: Agency Response to RRTF Correspondence

Dear Ms. Bergeson:

The purpose of this letter is to summarize and respond to all correspondence I have received from the Rodenticide Registrants Task Force (RRTF) regarding the ecological assessment since our March 20, 2002, meeting. But first, I think it would be helpful to provide some background on the issue of risks to birds and non-target mammals.

When the rodenticide cluster and zinc phosphide REDs were issued in 1998, EPA noted that recent information had come to the Agency's attention regarding potential adverse effects to birds and non-target mammals. The 1998 Rodenticide Cluster RED stated that EPA planned to further evaluate these potential risks to determine if additional risk mitigation is needed before concluding that uses are eligible for reregistration.

The RRTF formed in late 1998 following the release of the draft Rodenticide Cluster RED. Since 1999, the RRTF has participated in many meetings with the Agency to address issues of shared concern regarding the evaluation and use of rodenticides. In October 1999 EPA held an all-day public meeting during which EPA presented a comparative approach to ecological assessment for rodenticides. States, industry, and environmental groups also presented their perspectives on ecological risk, and public comments were provided. EPA decided to use a public participation process to continue to ensure broad stakeholder input on the risk assessment and any resulting mitigation options.

In November 2001 EPA completed its preliminary ecological risk assessment, "*Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals*," and initiated the first phase of the public participation process: error-only review of the assessment by the registrants. Since September 2001, the Agency has agreed to meet with you on five separate occasions to listen to and discuss the RRTF's concerns with the preliminary assessment, most recently with Marcia Mulkey on October 9, 2002.

As discussed at the October 9 meeting, EPA has made several revisions to the preliminary assessment based on the RRTF's comments, and has prepared written responses to comments submitted by the RRTF and each of the individual registrants during the error-only comment period.

I would like to note again, as we have during each of our meetings, that many of these comments relate to general risk assessment methodology, science policy, or interpretation of the data which are generally not addressed during error-only review. EFED has, however, added a great deal of characterization to the assessment to address your comments. Regarding correspondence from you since our meeting in March:

In your March 25, 2002, letter (as a follow up from the 3/20 meeting) you summarized the next steps outlined during the meeting:

1. The RRTF would resend error comments.
2. EPA would evaluate the comments, prepare responses, and update the preliminary assessment as appropriate.
3. EPA would consider the RRTF's comments on field v. commensal use patterns.
4. The RRTF would submit support for its position that the assessment is not a risk assessment.
5. EPA would identify additional use information that would be helpful.
6. The RRTF would submit a bibliography of critical information not cited or selectively cited.

In response to this letter, the Agency has considered all error comments and revised the assessment as appropriate. These considerations are embodied in the revised assessment and responses to error comments which are also being made available for public comment during Phase 3 of the public participation process. EPA has also considered the comments relating to use patterns and has identified in the current document additional data that would be useful for refining the risk assessment. Also, as Marcia Mulkey agreed at your meeting with her on October 9, EPA will provide the RRTF a courtesy copy of the response to its error comments shortly before opening the public docket.

Your April 12, 2002, letter was a response to the Agency's letter of March 27, 2002, regarding handling of the RRTF's error comments on the preliminary risk assessment. The RRTF sought assurances that EPA would fully consider technical comments and supplemental materials in revising the assessment and provide the RRTF the response to comments discussed at the March 20, 2002, meeting.

In response to this letter, I regret that there were problems with the submission and processing of your error comments. After receiving a resubmitted hard copy, however, EPA has considered all technical comments and supplemental materials. As noted above, we will provide the RRTF a copy of the response to comments, which will also be placed in the public docket.

Your April 15, 2002, letter is a compilation listing documents the RRTF submitted to EPA from 1999 to 2002 with regard to risks to birds and nontarget animals.

In response, EPA has considered all relevant documents in developing and revising the assessment. Documents which did not contain relevant risk information, such as those relating to benefits, were not considered.

Your April 22, 2002, letter references risk-benefit considerations. Appended to the letter was a copy of an article, “Risk-Benefit Considerations In Evaluating Commensal Anticoagulant Rodenticide Impacts To Wildlife,” which includes information on pounds of active ingredient by market segment.

In response, the Agency will consider benefits information when considering risk management options. Information on market preferences for current products, and pounds produced or imported have been considered, though more detailed data would be useful for further refining use patterns as they relate to specific products and potential risks to birds and non-target mammals.

Your second April 22, 2002, letter contained a correction and clarification to the RRTF’s error comments on the preliminary assessment. Consequently, you requested that the Agency supplement the record with this clarification.

In response, the supplemental information you provided has been reviewed and considered in the revised assessment and in EPA’s response to comments.

Your May 1, 2002, letter is a supplement to the RRTF’s comments on the preliminary assessment and lists reasons why the RRTF believes the assessment should not provide a basis for EPA decision-making. In addition, you indicate that you will provide a bibliography of those studies that the RRTF believes should have been considered, referenced, and cited in the assessment (see May 9, 2002, letter). You state that the assessment:

- is not consistent with ecological risk assessment guidance.
- is not consistent with methodology and purposes for other comparative assessments, or with guidance from the SAP.
- does not consider exposure or use patterns, so it should not be used to determine if exposure reduction measures are needed.
- uses a methodology criticized by the SAP and does not incorporate changes suggested by the SAP.

In response to these four concerns:

- EPA has relied on current guidelines and policies for ecological risk assessment in preparing the current assessment, and has explained the methodology in more detail in the revised introduction to the assessment. Further, EPA notes that it has evaluated each rodenticide individually using standard ecological risk assessment methods and believes, based on these evaluations, that the rodenticides pose high absolute risk to non-targets. The central purpose of this assessment is to rank them in terms of potential primary, secondary, and overall risk to non-targets which can lead to efficient risk management.
- The methodology used in this assessment is similar to that used in the Agency’s “Comparative Analysis of Acute Risk From Granular Pesticides” (EPA 1992) and “A Comparative Analysis of Ecological Risks From Pesticides and Their Use: Background, Methodology, Case Study” (EPA 1998). In the current analysis, risk quotients (RQs), are used to compare potential primary risks to birds and non-target mammals. As noted by the

Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM 1999), RQs do not quantify risk but are useful for comparisons among alternative compounds. In addition, quotients also provide an efficient, inexpensive means of identifying high- or low-risk situations that can allow risk management decisions to be made without the need for further data. Finally, EPA notes that it has relied on the SAP's comments on other comparative assessments in developing the current assessment (see below).

- Data to further refine and quantify exposure to non-target wildlife are currently not available. In the current assessment risk conclusions are based on a "weight-of-evidence" approach which includes a number of measures including RQs, incidents, etc., and data also are compared and evaluated by means of a comparative analysis model. According to EPA's risk assessment guidelines (EPA 1998), professional judgement or other qualitative evaluation techniques may be used to rank risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms.
- EPA has considered the SAPs comments and incorporated several of their recommendations including those described as critical in developing this assessment. Although the SAP noted many scientific uncertainties in the comparative method, they agreed that is a useful screening tool that provides a rough estimate of relative risk. EPA notes that the role of the SAP is to advise, not direct, EPA. Finally, it is important to remember that the Ecological Risk Assessment Guidelines describe a possible outcome of comparative risk assessments as focusing limited resources on areas having the greatest risk reduction potential.

Your May 9, 2002, letter is a follow up item from our March 20, 2002, meeting which provides the bibliography of studies the RRTF believes were not cited, were cited selectively, or were misinterpreted in the preliminary assessment.

In Response, the relevant studies and articles in the bibliography you provided have been reviewed, incorporated, and cited, as appropriate, in the revised assessment.

Your May 22, 2002, letter expresses your concerns regarding the January 2001 peer review that was conducted on EPA's draft preliminary assessment. Included in your letter are excerpts from EPA's "Peer Review Handbook" from which you based your arguments.

In response, the Agency has summarized and responded to the peer review comments consistent with guidance provided in the Agency's Peer Review Handbook (updated December 2000). The peer review comments and EPA's responses are available in the public docket.

In conclusion, after considering the comments from the RRTF and listening to the registrants' concerns, EPA believes that at this point all comments and concerns have been adequately incorporated (where applicable) into the current assessment. We believe, as discussed during the October 9 meeting, it is appropriate and important to now obtain comment from all stakeholders and the scientific community on the preliminary assessment. Therefore, we have decided to move forward with the next phase of the process and publish the preliminary assessment for public comment. As Marcia agreed, we will send you a courtesy copy of the responses to your

comments before publishing the revised preliminary assessment.

Sincerely yours,

Lois Rossi, Director
Special Review and Reregistration Division